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| 09/845,898 | 04/30/2001 | Ronald J. Kolata | 102863-2 | 4070 |

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EXAMINER

RAMANA, ANURADHA

| | |
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| ART UNIT | PAPER NUMBER |
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3751

DATE MAILED: 08/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,898

Applicant(s)

KOLATA ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. See attached Form PTO-948.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “detents” of claim 12 must be shown or the features canceled from the claim. No new matter should be entered.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “82 b” has been used to designate different openings. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: “body 13”. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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Specification

The disclosure is objected to because of the following informalities: Different parts of instrument 10 are being referenced by the same number. For example, Page 8, lines 3 and 7, “body 13” and line 8 “pivot 13.” Appropriate correction of the entire text of the disclosure is required.

On page 12, line 22, it appears that “housing 13” should be “housing 12.”

On page 12, line 23, it appears that “element 40” should be “element 14.”

Appropriate correction of the entire text of the disclosure is required to ensure that the invention is clear.

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The specification is also objected to as failing to provide proper antecedent basis for the claimed subject matter "detents" of claim 13. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the tissue grasping element can be fully disposed within the inner lumen of the body in the open position. Figure 3 shows the tissue grasping element in a closed position.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce (US 5,893,878) in view of Li (US 5,954,057).

Pierce discloses a medical instrument with a body 10, a tissue grasping element 18 with two opposed tissue grasping claws or members 26 and 28, selectively openable between an open or a closed position, and an actuating member 32 mated to body 10 and effective in moving claws 26 and 28 between the retracted and extended positions (Figure 1 and col. 4, lines 10-22).

Pierce does not disclose a flexible member having a portion secured to body 10 with one free end that is fastenable to a support.

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Li teaches a suspending tissue from a bodily support structure utilizing a flexible member or strap attached to a tissue penetrating structure (col. 3, lines 31-45, Figure 4, Figure 16 and Figure 17). Li further teaches that the suspension strap can be a wire, web, chain or the like (col. 14, lines 60-67).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a flexible member or strap secured to body 10 of the Pierce instrument wherein the other end of the strap may be attached to a support structure to suspend tissue grasped by instrument 10 as taught by Li. Further, the choice of the support structure would depend on how and where the grasped tissue needs to be suspended.

Regarding claim 3, Pierce discloses that handle 20 has opposed first (50) and second (52) members wherein a force applied to bring members 50 and 52 in contact with each other causes opening of claws 26 and 28 (col. 5, lines 24-33).

Regarding claim 4, Pierce discloses that the tissue grasping element 18 has claws or members 26 and 28 comprised of flexible metal and are normally in a biased open position (Figure 1). The bias of the grasping members would be selected in accordance with the application of the instrument 10 and would be a matter of obvious design choice.

Regarding claim 5, Pierce discloses that the contact member 18 can take a variety of shapes including circular wherein the shape selected depends on the intended use of the instrument 10 (col. 4, lines 27-35).

Regarding claim 7, Pierce discloses a hollow, applicator sleeve 12, slidably disposed on body 10 that selectively engages the actuating member. Pierce does not disclose that the sleeve is removable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the sleeve 12 removable since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Regarding claim 8, sleeve 12 engages the tissue grasping element 18 in a proximal position (Figure 6) and engages the tissue grasping element 18 in a distal position (Figure 7).

Regarding claim 11, see discussion for claim 4.

Regarding claims 13 and 14, Li shows an embodiment of clip 10, 200 (Figure 16) wherein the flexible member 212 is disposed in bore 234 of a core member 232 (col. 15, lines 17-21) (Figures 16 and 17) to enable hanging clip 10 from a support structure.

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Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the flexible member 212 in the inner lumen of the body of instrument 10 as taught by Li to support instrument 10 of Pierce from a support structure. Further, the actual connection of the flexible member as taught by Li to the instrument 10 of Pierce would be a matter of obvious design choice given that the flexible member is being utilized to suspend instrument 10 from a support structure.

Claim 37 is rendered obvious by the discussion above. The claimed method steps are inherently performed during the normal use of instrument 10 of Pierce for grasping tissue and then suspending the instrument 10 from a support structure utilizing a flexible member.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce (US 5,893,878 in view of Li (US 5,954,057), as applied to claim 11, further in view of Schmaltz et al. (US 6,050,996).

Pierce does not disclose detents.

Schmaltz et al. teach detents 29 and 30 (Figure 1) in an instrument 10 for grasping tissue between its jaws 19 and 20 wherein the detents hold strain energy in actuating members 13 and 14 to force jaws 19 and 20 in opposition (Figure 1, col. 2, lines 64-65, col. 4, lines 6-10 and lines 50-57).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided detents 29 and 30 in the actuating members 48, 50 and 52 to force jaws 26 and 28 of instrument 10 of Pierce in opposition as taught by Schmaltz et al.

Claims 16-32, 33, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce (US 5,893,878).

Regarding claims 16 and 32, Pierce discloses a medical instrument with a body 10, two tissue grasping claws 26 and 28, a shaft or member 12, a handle 20 mated to the second end of member 12, an actuating member 32 slidably communicating between the handle 20 and the tissue grasping claws 26 and 28, effective in moving the claws 26 and 28 between the retracted and extended positions (col. 4, lines 10-27). Pierce also discloses a lever 48, 50 movably disposed in handle 20 and attached to the actuating member 32, effective in moving the actuating

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member 32 and the tissue grasping claws 26 and 28 between the retracted and extended positions. Pierce does not disclose that member 12 is flexible (Figure 4, col. 4, lines 51-67 and col. 5, lines 1-33).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made member 12 flexible, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Regarding claims 17-19, 21-23, and 27 Pierce does not disclose a wire or a cable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the rod 32 with a wire or a cable, since the examiner takes Official Notice of the equivalence of a wire and a rod for connecting two members and the selection of any of these known equivalents to connect handle 20 to element 18 would be within the level of ordinary skill in the art.

Regarding claim 19, tissue grasping claws 26 and 28 in instrument 10 of Pierce are normally biased to the open position (Figure 1).

Regarding claims 21 and 35, Pierce discloses that the tissue grasping element may take the form of a pad with a variety of shapes, including circular and elliptical, the exact configuration depending on the intended use of the instrument 10 (col. 4, lines 27-35). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the body of instrument 10 substantially disk shaped to match its intended use.

Regarding claims 22 and 36, Pierce further discloses that body 10 has a member 12 which is hollow or has an inner lumen.

Regarding claim 23, Pierce discloses the tissue grasping element or claws 26 and 28 to be disposed within the inner lumen of body 10 (Figure 8).

Regarding claim 24, Pierce discloses a tissue grasping instrument with a body 10 and a member 12. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the several pieces or elements integral since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. It would have been obvious to one having ordinary

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skill in the art at the time the invention was made to have made member 12 rigid, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Regarding claim 25, Pierce shows tissue grasping element 18 and members 26 and 28 to be extendable from the distal end of the instrument body (Figures 1, 6 and 7).

Regarding claims 26-28, see discussion for claims 18 and 21.

Regarding claim 33, Pierce discloses that the tissue grasping claws or members 26 and 28 are comprised of flexible metal and are normally in a biased open position (Figure 1). The bias of the grasping member would be selected in accordance with the application of the instrument 10 and would be a matter of obvious design choice.

Claims 20 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce (US 5,893,878), as applied to claims 19 and 33, further in view of Whipple et al. (US 4,522,206).

Pierce does not disclose a latch disposed on the handle 20 of instrument 10 that is selectively engageable with the levers 48 and 50 for releasably locking the tissue grasping element 26 and 28 in one of the retracted or extended positions.

Whipple et al. teach a handle 64 with an actuating lever 20 wherein a latch 72 is configured to engage trigger 20 to fix jaws 2 and 4 (Figure 1) at selected positions, e.g. fully closed, without having to maintain pressure on the trigger 20 (Figure 3b and col. 5, lines 17-26).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a latch 72 as taught by Whipple et al. to engage levers 48 and 50 in the handle 20 of Pierce so that jaws 26 and 28 can be held at selected positions without having to maintain pressure on levers 48 and 50.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce (US 5,893,878), as applied to claim 28, further in view of Rapacki et al. (US 5,569,274).

Pierce does not disclose a gear assembly for moving tissue grasping element 26 and 28 with respect to rod or cable 32.

Rapacki et al. teach an actuating mechanism 13 for an introducer or device 1 wherein axial motion of shaft 3 relative to handle 11 of introducer 1 is enabled by the actuating

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mechanism 13. Rapacki et al. further disclose that the actuating mechanism can be a rotatable knob "or gear assembly" for converting rotational motion into axial motion (Figure 1 and col. 7, lines 3-9).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a gear assembly as taught by Rapacki et al. to move cable 32 thereby moving tissue grasping element 26 and 28 between the retracted and extended positions.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce (US 5,893,878) in view of Rapacki et al. (US 5,569,274), as applied to claim 29, further in view of Henderson et al. (US 5,674,228).

Pierce does not disclose a biasing element mated to the levers 48 and 50 or a biasing element mated to the tissue grasping element 26 and 28 wherein the biasing element biases either levers 48 and 50 or tissue grasping element 26 and 28 to one of the open or closed positions.

Henderson et al. teach a spring 42 mated to two members 20 and 26 to maintain a clamp 10 in its open position (Figure 1 and col. 5, lines 1-7).

The use of a spring is well known as a biasing element to keep two members in an open or closed position.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a spring or biasing element 42 as taught by Henderson et al. in the instrument 10 of Pierce as modified by Rapacki et al., to bias two members in an open or closed position, wherein the two members are either the jaws 26 and 28 or the levers 48 and 50.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached on 8:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on (703) 308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0975.

AR

August 20, 2002



TIMOTHY L. MAUST
PRIMARY EXAMINER